

National Commission for the Protection of Human Subjects  
of Biomedical and Behavioral Research

Westwood Building, Room 1  
5333 Westbard Avenue  
Bethesda, Maryland 20814

August 24, 1977

Honorable Daniel K. Inouye  
Chairman, Select Committee  
on Intelligence  
Dirksen Senate Office Building  
Room G-308  
Washington, D.C. 20510

Dear Senator Inouye:

Recently the Commission for the Protection of Human Subjects was asked by the National Foreign Intelligence Board to review draft "Guidelines for Human Subject Research Within the Intelligence Community." In our response (a copy of which is enclosed) the Commission made two comments that I would like to bring to your attention.

First, the Commission stressed the need to assure that human rights will be protected in classified research. We noted that the promulgation of the Guidelines (which essentially adopt DHEW regulations for institutional review, informed consent, etc.) would clarify basic policies for the protection of human subjects, but would carry little force or authority beyond that of exhortation. The Commission suggested that adherence to the provisions of the Guidelines should be required at least by Executive Order and, preferably, by legislation. Such steps are necessary to provide reasonable assurance that the Guidelines will in fact be followed by intelligence agencies conducting or supporting research involving human subjects. (E.O. 11905 already requires that drug experimentation by foreign intelligence agencies must conform with guidelines issued by the Commission for the Protection of Human Subjects.)

Second, the Commission recommended that classified research requiring review by an Institutional Review Board composed entirely of members with security clearance should undergo a second review by this Commission or its successor. Alternatively, such review could be conducted by the select Congressional committees having oversight of Intelligence Community activities. This additional review would strengthen monitoring of classified research and would also enhance public confidence that ethically unacceptable research will not be conducted in the future.

I hope that the above information will be useful to you.

Sincerely yours

Chairman